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APPLICATION NO.		FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
	10/528,081	1832 7590 07/25/2007		Daniel Baumgartner	8932-1174-999	5827
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	222 EAST 41S			•	SCHILLINGER, ANN M	
	NEW YORK,	NY 10017-6702			ART UNIT	PAPER NUMBER
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					07/25/2007	PAPER .

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

•	Application No.	Applicant(s)					
<b></b>	10/528,081	BAUMGARTNER ET AL.					
Office Action Summary	Examiner	Art Unit					
	Ann Schillinger	3738					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1)⊠ Responsive to communication(s) filed on 11 Max     2a)⊠ This action is FINAL. 2b)□ This     3)□ Since this application is in condition for alloware closed in accordance with the practice under Expression is the condition of the condit	action is non-final. nce except for formal matters, pro						
Disposition of Claims							
4) □ Claim(s) 1-15 and 19-34 is/are pending in the a 4a) Of the above claim(s) is/are withdray 5) □ Claim(s) 19-34 is/are allowed. 6) □ Claim(s) 1-15 is/are rejected. 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and/or	vn from consideration.						
Application Papers							
9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. § 119							
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: <u>Attachmenst</u>	ate atent Application					

Application/Control Number: 10/528,081

Art Unit: 3738

#### **DETAILED ACTION**

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Marnay et al. (U.S. Pat. No. 6,936,071). Marnay et al. discloses the following of claim 1: an intervertebral implant, comprising: (A) two articulating parts (4, 10) each having a central axis (see Attachment A), each having a slide surface (12, 25) intersecting the central axes (see Attachment A) and each having an outermost end (2, 3, 24) that can be connected to a bone (col. 5, lines 44-49), wherein: (B) the slide surfaces (see Figure 7) are curved, (C) the slide surfaces are mutually displaceable (col. 5, lines 25-26), and (D) the second slide surface (10) is rotatable about two skewed axes of rotation relative to the first articulating part (see Attachment A), (E) the outermost ends of the articulating parts each comprise a connection element (body portions of elements 2 and 3), wherein: (F) at least one of the connecting element is fitted with an oval recess (space where element 4 is located) coaxial with the central axis, the at least one oval recess being sized and configured to receive one of the outermost ends of the adjoining articulating part (see Figure 7); wherein: (G) the recess is fitted with an axially terminal cavity (19) and the adjoining outermost end of the adjacent articulating part comprises a widening (26) coaxial with the central axis, said widening being insertable into the cavity so that said at least one articulating part is slidably

displaceable with respect to said adjoining connecting element (col. 5, lines 9-16), and (H) the slide surfaces are saddle-shaped (see Figure 7). It should be noted that the examiner is interpreting the claim language of the "two skewed axes of rotation" to potentially be any axis in space, which the reference element 10 is capable of rotating around. The axes shown in Attachment A are meant merely to illustrate two such axes, and is not intended to limit the interpretation of these axes to those locations alone.

Page 3

Marnay et al. discloses the following of claim 2: the implant as claimed in claim 1, wherein the slide surfaces each comprise a saddle point (see Attachment A).

Marnay et al. discloses limitations of claims 3-5 because the axes of rotation may be located anywhere element 10 is capable of rotating around, the axes may be drawn with the limitations as described in these claims.

Marnay et al. discloses the following of claim 6: the implant as claimed in claim 1. wherein the slide surfaces (12, 25) each comprise a saddle-point (see Attachment A) and wherein, when the second articulating part (10) is rotated about either one of the axes of rotation (see Attachment A), the second saddle point (saddle point as reference to element 10) moves along an arc of circle concentric with said either one of the exes of rotation (as shown in Figure 7, element 10 will slide along the track created for it by element 4, which is an arc of a circle, and an axis of rotation may be appropriately drawn to be concentric with it).

Marnay et al. discloses the following of claim 7: the implant as claimed in claim 1, wherein, in an initial position, the slide surfaces are congruent at coaxial central axes of the articulating parts (see Attachment A, Figure 7).

Application/Control Number: 10/528,081 Page 4

Art Unit: 3738

Marnay et al. discloses the following of claim 8: the implant as claimed in claim 1, wherein the connection elements are designed as cover plates (col. 3, lines 64-65; col. 4, lines 9-10) having an axially outermost surface (5, 13) transverse to the central axes (see Attachment A).

Marnay et al. discloses the following of claim 9: the implant as claimed in claim 8, wherein one of the cover plates (2) is integral with the adjoining articulating part (10).

Marnay et al. discloses the following of claim 10: the implant as claimed in claim 8, wherein one of the cover plates (3) is fitted with a guide (27) perpendicular to one of the central axes (see Attachment A) and wherein the adjoining articulating part (4) comprises a rear end (lower portion of element 4) insertable into the guide (see Figure 7).

Marnay et al. discloses the following of claim 11: the implant as claimed in claim 1, wherein one of the articulating parts (4) is rotated about its central axis in order to be assembled to the associated connection element (col. 5, lines 11-14). Please note that in the amendment filed on 5/11/2007, claim is listed as being amended, but no changes were made to the claim.

Marnay et al. discloses the limitations of claims 12 and 13 in that element 10 would begin at a plane perpendicular to its central axis for it to then be moved and assembled on top of elements 3 and 4.

Marnay et al. discloses the following of claim 14: the implant as claimed in claim 1, wherein one of the articulating parts is made of plastic (col. 5, lines 34-37).

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 3738

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marnay et al. in view of Ferree et al. (U.S. Pub. No. 2004/0024462). Marnay et al. discloses the invention substantially as claimed, however, Marnay et al. does not disclose using ceramic to make part of the implant. Ferree et al. teaches to use ceramics when making an intervertebral implant in paragraph 0005 for the purpose of decreasing the wear on the implant. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use ceramics when making the implant in order to increase the longevity of the implant by utilizing the ceramics' low wear characteristics.

Claims 19-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferree (US Pat. No. 6,706,068) in view of Songer et al. (U.S. Pat. No. 6,682,561). Regarding claims 19-22, 25-30, and 32-34, Ferree discloses most of the limitations of these claims 19 as shown in Attachment B; col. 2, line 62 through col. 3, line 6; and in Figures 1-5. However, Ferree probably does not disclose making the first plate and the first member separate pieces. Songer et al. teaches this in col. 1, line 45 through col. 2, line 60 and Figures 1-4 for the purpose of allowing the implant to be adjustable to the patient. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the plate and first member separate pieces in order to allow the implant to be adjustable to the patient.

In addition, it would be obvious to one having ordinary skill in the art at the time the invention was made to make the first plate and first member separate, since it has been held that

Art Unit: 3738

constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

Ferree discloses the limitations of claims 23 and 24 in col. 2, lines 9-15.

Ferree discloses the limitations of claim 31 in col. 3, lines 57-65.

### Response to Arguments

Applicant's arguments filed 5/11/2007 have been fully considered but they are not

persuasive. Regarding claims 1 and 15, the Applicant contends that the Marnay et al. reference

is not "saddle-shaped." Claim language is subject to the broadest reasonable interpretation. The definition of "saddle" is "a pass or ridge that slopes gently between two peaks" (saddle. Dictionary.com. WordNet® 3.0. Princeton University.

http://dictionary.reference.com/browse/saddle (accessed: July 19, 2007)). When viewed from overhead (best seen in Figure 7), the Marnay et al. reference has a shape that meets the requirements of this definition. The Applicant further contends that the Marnay et al. reference does not have an articulating surface slidably displaceable with respect to the adjoining connecting element. However, Marnay et al. in col. 5, lines 9-16 and Figure 1 describes how element 4 is put into the opening, element 19. The language of claim 1 does not specify that this

Applicant's arguments with respect to claims 19-34 have been considered but are moot in view of the new ground(s) of rejection.

process must occur when the implant has already been inserted.

#### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/528,081

Art Unit: 3738

Page 8

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger July 19, 2007

ALVIN J. STEWART PRIMARY EXAMINER

Attachment A Skewed

